**United States District Court**
**District of Massachusetts**

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|---|---|---|
| **Chr. Hansen HMO GmbH,** | ) | |
| **Plaintiff and Counterclaim-Defendant,** | ) | |
| **v.** | ) | **Civil Action No. 22-11090-NMG** |
| **Glycosyn LLC,** | ) | |
| **Defendant and Counterclaim-Plaintiff,** | ) | |
| **v.** | ) | |
| **Abbott Laboratories,** | ) | |
| **Third-Party Defendant.** | ) | |

**MEMORANDUM & ORDER**

**GORTON, J.**

This case arises out of patent infringement claims brought by Glycosyn LLC ("Glycosyn") against Chr. Hansen HMO GmbH ("Chr. Hansen") relating to Chr. Hansen's method of manufacturing a human milk sugar known as 2'-fucosyllactose ("2'-FL"), which was an ingredient in certain infant formulas sold by Abbott Laboratories ("Abbott").[1] Chr. Hansen seeks a declaratory judgment that its manufacturing method does not infringe the

[1] The original manufacturer, Jennewein Biotechnologie GmbH, was acquired by Chr. Hansen HMO GmbH in 2021, and is therefore included in all further references to "Chr. Hansen".

claims in Glycosyn's U.S. Patent No. 9,970,018 ("the '018 patent") and that furthermore those claims are invalid.

This memorandum and order addresses only issues of claim construction and follows submission by the parties of claim construction briefs, responsive pleadings and the Markman hearing held on January 10, 2024. The parties dispute two terms in the '018 patent.

## I. Background

### A. History of the Parties

Glycosyn and Chr. Hansen have been embroiled in litigation for nearly six years. In March, 2018, Glycosyn filed suit against Chr. Hansen in the District of Massachusetts for patent infringement but that suit was stayed pending resolution of a parallel action brought by Glycosyn one month later at the International Trade Commission ("ITC"). Glycosyn LLC v. Jennewein Biotechnologie GmbH, No. 18-cv-10423-PBS, Docket No. 1, 13 (D. Mass. Mar. 5, 2018).

In December, 2018, an administrative law judge ("ALJ") issued a claim construction order in the ITC action. In the Matter of Certain Hum. Milk Oligosaccharides & Methods of Producing the Same, 2018 WL 6837945, at *22-23 (U.S.I.T.C. Dec. 18, 2018) (hereinafter "ITC Construction Order"). The ALJ construed "functional β-galactosidase gene" to mean "a functional sequence of DNA that encodes β-galactosidase," id. at

*22-23, and "β-galactosidase activity comprises between 0.05 and [200 units / 5 units / 4 units / 3 units / 2 units]" as "β-galactosidase activity is measurable at between exactly 0.05 and exactly [200/5/4/3/2) Miller Units, as defined in Miller, J.H., Experiments in Molecular Genetics (Cold Spring Harbor Lab. 1912) at 352-355," id. at *18. A different ALJ of the ITC applied that construction order and determined that Chr. Hansen infringed certain claims of the Glycosyn patent under the doctrine of equivalents. 2019 WL 5677974 (U.S.I.T.C. Sept. 9, 2019) (hereinafter "ITC Initial Determination").

In May, 2020, the ITC issued a Limited Exclusion Order against Chr. Hansen after reviewing the ALJ's decision. The Federal Circuit Court of Appeals affirmed that decision in September, 2021 after finding the ITC "did not err in its claim construction or in its finding of infringement." Jennewein Biotechnologie GmbH v. Int'l Trade Comm'n, 2021 WL 4250784, at *1 (Fed. Cir. Sept. 17, 2021).

In June, 2022, Glycosyn voluntarily dismissed the 2018 District of Massachusetts suit and filed suit against Abbott in the United States District Court for the Western District of Texas for infringement of the '018 patent. Glycosyn LLC, No. 18-cv-10423-PBS, Docket No. 19; Glycosyn LLC v. Abbott Laboratories, No. 22-cv-00619-ADA, Docket No. 1 (W.D. Tex. June 14, 2022).

Chr. Hansen filed the pending declaratory judgment action in this Court against Glycosyn in July, 2022, seeking declaratory judgment of non-infringement and invalidity of the '018 patent. One month later, Glycosyn dismissed the Western District of Texas suit against Abbott and filed an answer and counterclaim against Chr. Hansen and a cross-claim against Abbott in the Massachusetts action. See Glycosyn LLC, No. 22-cv-00619-ADA, Docket No. 4.

In response, Abbott moved to sever and stay the claim against it pending resolution of the cross claims between Glycosyn and the manufacturer, Chr. Hansen. In March, 2023, this Court denied Abbott's motion to sever and stay after finding the customer suit exception and traditional stay factors inapplicable. Docket No. 47.

**B. The '018 Patent**

This matter revolves around the '018 Patent, which bears the name "Biosynthesis of Human Milk Oligosaccharides in Engineered Bacteria." That patent was filed on September 21, 2017 and issued on May 15, 2018. According to the patent, human milk contains a diverse set of human milk oligosaccharides ("HMOs") that support the establishment of healthy gut microbiome in infants. Scientists have historically been unable to develop HMOs inexpensively at scale.

The ’018 Patent purports to help solve that problem by engineering E. coli bacterial strains to produce fucosylated oligosaccharides (such as 2’-fucosyllactose, or “2’-FL”) which can be used in products, such as infant formula or dietary supplements. According to Glycosyn’s claim construction brief, bacteria are genetically modified

> (1) [to] increase the intracellular guanosine diphosphate (GDP)-fucose pool; (2) [to] increase the intracellular lactose pool; and (3) [to] add a fucosyltransferase that will bind a fucose to the lactose and thus form a fucosylated oligosaccharide such as 2’-FL.

β-galactosidase is one enzyme that can break a molecule into two parts. For example, β-galactosidase can break down lactose into galactose and glucose. β-galactosidase, which breaks down a lactose, and fucosyltransferase, which uses lactose to create fucosylated oligosaccharides, can conflict with one another.

To ensure the availability of lactose for the fucosyltransferase reaction, which can result in the creation of needed fucosylated oligosaccharides, the intracellular lactose pool must be increased. To do that, the engineered bacterium is modified to delete or functionally inactivate the β-galactosidase gene (referred to as “lacZ”) in such a way that the downstream lactose permease (“lacY”) gene is left intact.

While some elimination of β-galactosidase is helpful when producing fucosylated oligosaccharides, complete elimination can result in purification issues later in the manufacturing process. Accordingly, the engineered bacterium includes an exogenous functional β-galactosidase gene "to direct the expression of a low, but detectable level of β-galactosidase activity."

According to the patent, this results in low levels of β-galactosidase activity between 0.05 and 200 Miller units. At that level, the β-galactosidase activity is not too low to create purification issues nor too high to diminish the intracellular lactose pool needed to produce fucosylated oligosaccharides. In essence, the process produces a "Goldilocks" outcome.

Claim 1 of the '018 patent describes Glycosyn's method for producing a fucosylated oligosaccharide in an engineered E. coli bacterium. The key disputed terms are written below in bold:

> 1. A method for producing a fucosylated oligosaccharide in a bacterium, comprising providing an isolated E. coli bacterium comprising,
> (i) a deletion or functional inactivation of **an endogenous β-galactosidase gene**;
> (ii) an exogenous functional β-galactosidase gene comprising a detectable **level of β-galactosidase activity** that is reduced compared to that of a wildtype E. coli bacterium, **wherein the level of β-galactosidase activity comprises between 0.05 and 200 units**;

> (iii) an inactivating mutation in a colanic acid synthesis gene; and
> (iv) an exogenous lactose-accepting fucosyltransferase gene; culturing said bacterium in the presence of lactose; and retrieving a fucosylated oligosaccharide from said bacterium or from a culture supernatant of said bacterium.

(Emphasis added.)

## II. Terms

### A. Overview of Claim Construction

In analyzing a patent infringement action, a Court must 1) determine the meaning and scope of the patent claims asserted to be infringed and 2) compare the properly construed claims to the infringing device. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). The first step, known as claim construction, is an issue of law for the court to decide. Id. at 979. The second step is determined by the finder of fact. Id.

The Court's responsibility in construing claims is to determine the meaning of claim terms as they would be understood by persons of ordinary skill in the relevant art. Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc., 262 F.3d 1258, 1267 (Fed. Cir. 2001). The meaning of the terms is initially discerned from three sources of intrinsic evidence: 1) the claims themselves, 2) the specification and 3) the prosecution history of the patent. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582-83 (Fed. Cir. 1996).

The claims themselves define the scope of the patented invention. See Philips v. AWH Corp., 415 F.3d 1303, 1312 (Fed Cir. 2005). Claim terms are generally given their "ordinary and customary meaning", which is the meaning that a person skilled in the art would attribute to the claim term. See id. at 1312-13. Even if a particular term has an ordinary and customary meaning, however, a court may need to examine the patent as a whole to determine if that meaning controls. Id. at 1313 ("[A] person of ordinary skill in the art is deemed to read the claim term ... in the context of the entire patent...."); see also Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005) (noting that a court cannot construe the ordinary meaning of a term "in a vacuum"). Ultimately, the correct construction will be one that "stays true to the claim language and most naturally aligns with the patent's description of the invention...." Id. at 1316 (citation omitted).

> The patent specification is
>
> > the single best guide to the meaning of a disputed term [and may reveal] a special definition given to a claim term that differs from the meaning it would otherwise possess [or contain] an intentional disclaimer, or disavowal, of claim scope by the inventor.

Phillips v. AWH Corp., 415 F.3d 1303, 1313-16 (Fed. Cir. 2005) (en banc) (cleaned up). The Court should also consult the prosecution history to see how the inventor and PTO understood

the patent and to ensure the patentee does not argue in favor of an interpretation it has disclaimed. Id. at 1317.

In the rare event that analysis of the intrinsic evidence does not resolve an ambiguity in a disputed claim term, the Court may consider extrinsic evidence, such as inventor and expert testimony, treatises and technical writings. Id. at 1314; Markman, 52 F.3d at 980 ("The court may, in its discretion, receive extrinsic evidence in order to aid the court in coming to a correct conclusion as to the true meaning of the language employed in the patent." (internal quotation marks and citation omitted)). Although extrinsic evidence may be helpful in construing claims, the intrinsic evidence is afforded the greatest weight in determining what a person of ordinary skill in the art would have understood a claim to mean. Phillips, 415 F.3d at 1324.

**B. Level of the Person of Ordinary Skill in the Art**

The parties provide the same definition for the person of ordinary skill in the art ("POSITA") for the purposes the '018 patent. It is:

> a person having a Ph.D. in molecular biology, biochemistry, biological or chemical engineering, or an equivalent field, and 1-2 years of experience working with E. coli bacteria or related systems. Alternatively, a person of ordinary skill could have a lower level degree (e.g., a M.A.) in a similar field to those listed above, but a greater amount of relevant working experience (e.g., 5-6 years of

experience working with E. coli bacteria or related systems).

**C. Undisputed Terms**

The parties agree on the construction of the following terms of the '018 patent:

| Term | Asserted Claims of the '018 Patent | Proposed Construction |
|---|---|---|
| "wild-type" | Claims 1, 24 | Plain and ordinary meaning, i.e. "the type most commonly found in nature" |
| "colanic acid synthesis gene" | Claims 1-3 | "a gene involved in a sequence of reactions, usually controlled and catalyzed by enzymes that result in the synthesis of colanic acid" |
| "E. coli lacZ gene" | Claim 8 | Plain and ordinary meaning, i.e. "a structural gene that encodes the β-galactosidase protein and is part of the lac operon in the DNA of E. coli" |

**D. Disputed Terms**

There are two disputed terms at issue, which are hereinafter dealt with sequentially.

| Disputed Term #1 | Glycosyn's Construction | Chr. Hansen & Abbott's Construction |
|---|---|---|
| "[an] exogenous functional β-galactosidase gene" | Plain and ordinary meaning, i.e., "contiguous or non-contiguous DNA, | "a single functional sequence of DNA, originating outside the E.coli |

| | | |
|---|---|---|
| ('018 patent claims 1, 8, 23, 24) | originating outside the E. coli bacterium, that encodes for a working β-galactosidase enzyme" | bacterium, that encodes a working β-galactosidase enzyme" |

The parties agree that "exogenous" means "originating outside the organism" and that a "functional β-galactosidase gene" must encode a working β-galactosidase gene. The parties disagree about what a "gene" is for the purposes of the '018 patent.

**1. Glycosyn**

Glycosyn urges the Court to adopt the plain and ordinary meaning of "gene," a term it contends can refer to contiguous or non-contiguous DNA. Glycosyn acknowledges that the ITC construed the term "functional β-galactosidase gene" to mean "a functional sequence of DNA that encodes β-galactosidase," ITC Construction Order, 2018 WL 6837945, at *22-23, but notes that neither party included the word "sequence" in their own preceding proposed claim construction.

Glycosyn contends that the ITC's use of "sequence" is contrary to the basis of the field art because a gene is merely a "basic unit of inheritance." The patent is designed to cover a variety of β-galactosidase genes from "any number" of organisms. The patentee did not circumscribe the meaning of

gene by including limiting qualifiers such as "contiguous" or "sequence."

Glycosyn highlights extrinsic evidence that it contends bolsters its construction. Specifically, it identifies two examples of non-contiguous DNA: "introns" and the LacZ gene. Introns are internal sequences in protein-producing genes that do not encode for the resulting functional protein. The LacZ gene can be separated into two sequences of DNA: LacZα and LacZΩ. According to Glycosyn, LacZα and LacZΩ comprise an entire sequence of DNA that can still produce a working β-galactosidase enzyme despite being non-contiguous DNA. The LacZα and LacZΩ genes encode for different β-galactosidase peptides. When both peptides are present, they spontaneously assemble into a working β-galactosidase enzyme. This is known as "α-complementation."

Glycosyn finally contends that because Chr. Hansen and Abbott do not offer the plain and ordinary meaning of the term when read in the context of the intrinsic record, they must satisfy one of two exceptions: lexicography and disavowal. See Thorner v. Sony Comput. Ent. Am. LLC, 669 F.3d 1362, 1365 (Fed. Cir. 2012). Chr. Hansen and Abbott respond that those exceptions are inapplicable because they seek to offer the plain and ordinary meaning of the term.

At the Markman hearing, Glycosyn's counsel allowed that the ITC construction would be acceptable but that inclusion of the term "contiguous" or "single" would impose unwarranted limiting qualifiers.

**2. Chr. Hansen and Abbott**

Chr. Hansen and Abbott propose that the construction should be "a single functional sequence of DNA" because that comports with the ITC's construction. They cite authority that explains that "[w]hile not binding, the previous claim construction of the [] patent should be consulted." See Trustees of Bos. Univ. v. Everlight Elecs. Co., 23 F. Supp. 3d 50, 62 (D. Mass. 2014). They also cite dictionary definitions that define a gene as "a distinct sequence", "a sequence of DNA" and "the sequence of nucleotides of DNA." See Phillips, 415 F.3d at 1318 ("Within the class of extrinsic evidence, . . . dictionaries and treatises can be useful in claim construction.").

Chr. Hansen and Abbott reject the notion that a POSITA would understand "gene" to imply a non-contiguous sequence of DNA. They note that the ITC previously considered such an argument and determined that "a plain and ordinary meaning of sequence does imply contiguity." ITC Initial Determination, 2019 WL 5677974, at *28 (cleaned up). They contend that Glycosyn's proffered construction serves as an end-around of the ITC's determination and that Glycosyn's own expert, Dr. Kristala L.

Jones Prather, repeatedly described a gene as "a sequence of DNA" in declarations and witness statements both during the ITC proceeding and before this Court.

Finally, Chr. Hansen and Abbott reject Glycosyn's reliance on introns and LacZ as examples of genes that are made up of non-contiguous DNA. They cite dictionary definitions that suggest that an intron is merely a component of a gene rather than a gene itself and assert that Glycosyn brings up LacZα and LacZΩ now only because the accused strain of Chr. Hansen used to produce 2'-FL relies on α-complementation to produce β-galactosidase enzyme. Essentially, they accuse Glycosyn of arguing an infringement issue at claim construction, which is improper. See SRI Int'l v. Matsushita Elec. Corp. of Am., 775 F.2d 1107, 1118 (Fed. Cir. 1985).

**3. Analysis**

The Court begins with careful consideration of the construction adopted by the ITC and left untouched by the albeit unreported Federal Circuit opinion. While all parties agree that this Court is not bound by the ITC construction, it may afford it whatever persuasive value and deference it deems appropriate. See Texas Instruments, Inc. v. Cypress Semiconductor Corp., 90 F.3d 1558, 1569 (Fed. Cir. 1996).

As noted supra, the ALJ in the ITC proceeding construed "functional . . . β-galactosidase gene" as "a functional

sequence of DNA that encodes β-galactosidase." ITC Construction Order, 2018 WL 6837945, at *22-23.

At the Markman hearing before this Court, Glycosyn initially quibbled with the ITC's inclusion of the word "sequence" but ultimately accepted the ITC construction which aligns with that of Chr. Hansen and Abbott. They construe the term to mean a "singular functional sequence of DNA," but conceded at the Markman hearing that the word "singular" is redundant because "sequence" is a singular noun. Glycosyn, for its part, emphasizes that none of the dictionary definitions cited by Abbott and Chr. Hansen includes the word "single". Thus neither party provides a compelling reason to depart from the ITC construction.

In light of the ITC construction and perhaps reluctant concessions of the parties at the Markman hearing, resolution of the first disputed term is simplified. The Court will construe "functional . . . β-galactosidase gene" as "a functional sequence of DNA, originating outside the E. coli bacterium, that encodes a working β-galactosidase enzyme." The first clause follows the ITC construction, while the second and third adopt the constructions proffered by the parties.

| **Disputed Term #2** | **Glycosyn's Construction** | **Chr. Hansen & Abbott's Construction** |
|---|---|---|
| "the level of β-galactosidase activity comprises between 0.05 and [200 units / 5 units / 4 units / 3 units / 2 units]" ('018 patent claims 1, 18, 25-28) | Not indefinite;<br><br>"when a culture of the E. Coli bacteria comprising the exogenous functional β-galactosidase gene is assayed using the Miller protocol, β-galactosidase activity is measurable at between exactly 0.05 and exactly [200/5/4/3/2] Miller Units, as defined in Miller, J.H., Experiments in Molecular Genetics. Cold Spring Harbor Laboratory (Cold Spring Harbor, N.Y.; 1972) at 352-355" | Indefinite;<br><br>"β-galactosidase activity is measurable at between exactly 0.05 and exactly [200/5/4/3/2] Miller Units, as defined in Miller, J.H., Experiments in Molecular Genetics (Cold Spring Harbor Lab. 1972) at 352-355, where the β-galactosidase activity is the β-galactosidase activity attributable to the expression of the exogenous functional β-galactosidase gene only" |

With respect to the second disputed term, both parties recognize that this Court will address indefiniteness at the summary judgment stage. Docket No. 81-1. Accordingly, the parties did not brief that issue.

They agree that "units" means "Miller Units, as set forth in Miller, J.H., Experiments in Molecular Genetics (Cold Spring Harbor Lab. 1972) at 352-355." That term is defined in the patent specifications and the ITC and Federal Circuit both adopted that construction during the earlier proceeding.

**1. Glycosyn**

Glycosyn contends that its construction aligns with the plain and ordinary meaning of the claim term and emphasizes that

> if a company puts an exogenous functional β-galactosidase gene into a bacterial strain, and then performs the Miller protocol on the strain and gets results in the claimed range, the company practices this claim element.

Glycosyn suggests that even if it is not obvious on the face of the proffered constructions, the real dispute here is whether one may modify the Miller protocol when determining the claimed "units". It maintains that the ITC and Federal Circuit have already held that such modification is not permitted. Glycosyn further argues that nothing in the patent permits any changes to the Miller protocol, a proposition that Chr. Hansen purportedly agreed with during the Markman proceeding before the ITC.

Glycosyn accuses Chr. Hansen and Abbott of engaging in mischief by purposefully modifying the Miller protocol to avoid infringement. Specifically, it claims Chr. Hansen had a third party subtract negative control strains which is not permitted under the Miller Test protocol.

Glycosyn avers that the construction proffered by Chr. Hansen and Abbott will permit them to tinker with the Miller protocol under the pretense of discerning "activity attributable to the expression of the exogenous functional β-galactosidase

gene only." Glycosyn asserts that such construction will confuse the jury and insert unnecessary and uncontemplated verbiage into the '018 patent.

In its reply brief, Glycosyn emphasizes that the term "comprise", which appears in the claim at issue, is a term of art designed to broaden a claim. It argues that Abbott and Chr. Hansen "turn the law on its head" by suggesting that comprising restricts the patent to only β-galactosidase attributable to the inserted β-galactosidase gene. The patent is designed to claim that the

> inserted β-galactosidase gene, paired with anything else, could produce the claimed β-galactosidase activity so long as the β-galactosidase gene is present.

(Emphasis added.)

**2. Chr. Hansen and Abbott**

Chr. Hansen and Abbott contend that their proposed construction is supported by the patent, its specification and its file history.

First, the patent claims

> (1) a method for producing a fucosylated oligosaccharide in a bacterium, comprising . . . (ii) an exogenous functional β-galactosidase gene comprising a detectable level of β-galactosidase activity . . . .

That language purportedly demonstrates that only the "exogenous functional β-galactosidase gene," and nothing else,

is the source of the level of β-galactosidase activity. Chr. Hansen and Abbott suggest such terminology should end the inquiry because the plain text of the claim controls. See Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1248 (Fed. Cir. 1998).

Chr. Hansen and Abbott argue that the patent specification also supports their construction because it explains that the objective of the patent is

> achieved by utilizing a functional β-galactosidase (e.g., lacZ) gene insert carefully engineered to direct the expression of a low, but detectable level of β-galactosidase activity in an otherwise β-galactosidase negative host cell.

They question what is meant by Glycosyn's inclusion of the phrase "a culture of the E. Coli bacteria comprising the exogenous functional β-galactosidase gene". They suggest that 1) Glycosyn's construction is redundant because the parties have already agreed on the construction of "units", 2) the reference to "assay[ing] using the Miller protocol" could confuse the jury and 3) a second reference to the Miller protocol "would contribute nothing but meaningless verbiage." Harris Corp. v. IXYS Corp., 114 F.3d 1149, 1152 (Fed. Cir. 1997).

Chr. Hansen and Abbott reject Glycosyn's contention that the "real dispute" is whether it is appropriate to modify the Miller protocol. While Glycosyn seeks recognition by the Court that nothing in the patent permits changes to the Miller

protocol, Chr. Hansen and Abbott insist that the Court cannot decide at the claim construction stage what hypothetical changes to the Miller test are proper because that question relates to infringement.

**3. Analysis**

In their supporting memoranda, the parties resemble ships passing in the night. Chr. Hansen and Abbott focus on whether the measured β-galactosidase activity is attributable to the expression of the exogenous functional β-galactosidase gene only and suggest that Glycosyn doesn't really disagree with their proposed construction. Glycosyn, meanwhile, offers an entirely different understanding of the claim and focuses on whether it is appropriate to modify the Miller protocol.

The Court agrees with Glycosyn that Chr. Hansen and Abbott's use of "attributable to . . . only" would narrow the scope of the patent claim, a limitation that appears to be improper given the use of the term "comprising". See Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368 (Fed. Cir. 2003) (explaining that comprising "indicates that the claim is open-ended"). As counsel for Glycosyn noted at the Markman hearing, even if Chr. Hansen and Abbott are correct that the claimed β-galactosidase activity is the β-galactosidase activity attributable to the expression of the exogenous functional β-

galactosidase gene only, performing the Miller test as written should accomplish that. Additional verbiage would be redundant.

The Court also finds, however, that Glycosyn's inclusion of "assayed using the Miller protocol" is redundant given that the parties already have agreed on wording with respect to the Miller protocol.

The Court acknowledges the Federal Circuit's warning that "courts should not resolve questions that do not go to claim scope, but instead go to infringement," Eon Corp. IP Holdings v. Silver Spring Networks, Inc., 815 F.3d 1314, 1319 (Fed. Cir. 2016), and agrees with Chr. Hansen and Abbott that it would be improper to opine on whether the Miller protocol may be modified at this stage. As Glycosyn concedes, that issue is not addressed directly in the construction proffered by either party.

The Court returns again to the construction adopted by the ITC, which both parties implicitly acknowledge as being correct. No additional interpretation is necessary: the plain meaning of the ITC construction will do. Both parties seek to add additional verbiage to strengthen their infringement arguments rather than clarify the terms at issue. The Court declines to accept their invitation.

Accordingly, the term "the level of β-galactosidase activity comprises between 0.05 and [200 units / 5 units / 4

units / 3 units / 2 units]" will be construed as "β-galactosidase activity is measurable at between exactly 0.05 and exactly [200/5/4/3/2] Miller Units, as defined in Miller, J.H., Experiments in Molecular Genetics (Cold Spring Harbor Lab. 1972) at 352-355".

**ORDER**

In accordance with the foregoing,

1) the term "functional . . . β-galactosidase gene" means "a functional sequence of DNA, originating outside the E. coli bacterium, that encodes a working β-galactosidase enzyme".

2) the term "the level of β-galactosidase activity comprises between 0.05 and [200 units / 5 units / 4 units / 3 units / 2 units]" means "β-galactosidase activity is measurable at between exactly 0.05 and exactly [200/5/4/3/2] Miller Units, as defined in Miller, J.H., Experiments in Molecular Genetics (Cold Spring Harbor Lab. 1972) at 352-355".

**So ordered.**

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated February 15, 2024